

103  
5/20/15  
We claim:

1. A humanized monoclonal antibody that binds to Shiga toxin protein, comprising a constant region and a variable region, wherein said constant region contains at least part of a human immunoglobulin constant region and said variable region contains at least part of a non-human immunoglobulin variable region.

2. The humanized monoclonal antibody of claim 1, having the same binding specificity as the antibody selected from the group consisting of murine 13C4 (ATCC Accession No. CRL 1794), murine 11E10 (ATCC Accession No. CRL 1987), humanized 13C4 (H13C4), and humanized 11E10 (H11E10).

3. The humanized monoclonal antibody of claim 1, wherein the antibody binds Shiga toxin type 1.

4. The humanized monoclonal antibody of claim 3, wherein said non-human variable region is from the mouse.

5. The humanized monoclonal antibody of claim 3, wherein at least part of said variable region is from the sequences as set forth in Figure 3 (SEQ ID NO:19 and SEQ ID NO:21).

6. A fragment of the antibody of claim 3, wherein the fragment binds Shiga toxin type 1.

7. The humanized monoclonal antibody of claim 3, wherein said human constant region is selected from the group consisting of IgG, IgA and IgM.

8. The humanized monoclonal antibody of claim 7, wherein said human constant region is IgG.

9. A humanized monoclonal antibody which binds Shiga toxin type 1, comprising a constant region and a variable region, wherein:

said constant region is IgG1-kappa, and

said variable region contains at least part of the sequence as set forth in Figure 3

(SEQ ID NO: 19 and SEQ ID NO: 21).

10. A humanized monoclonal antibody which binds Shiga toxin type 1, comprising a constant region and a variable region, wherein:

said constant region is IgG1-kappa, and

said variable region contains at least part of the CDR sequences as set forth in Figure 3,

said CDR sequences located as follows:

Heavy Chain CDRs:

CDR1-aa31-35

(SEQ ID NO:19)

CDR2-aa50-66

CDR3-aa99-111

Light Chain CDRs:

CDR1-aa24-34

(SEQ ID NO:21)

CDR2-aa50-56

CDR3-aa89-97

11. An expression vector comprising a DNA sequence encoding the variable and constant regions of the light and the heavy chains of the antibody of claim 9, where the coding sequences for the variable regions contain at least part of the DNA sequences as set forth in Figure 3 (SEQ ID NO:18 and SEQ ID NO:20).

12. A host cell transformed with the expression vector of claim 11.

SP-101  
10-12  
13. The humanized monoclonal antibody of claim 1, wherein the antibody binds Shiga toxin type 2 and Shiga toxin type 2 variants.

SP-101  
10-12  
14. The humanized monoclonal antibody of claim 13, wherein said non-human variable region is from the mouse.

*B' added*  
<sup>15</sup>16. The humanized monoclonal antibody of claim 13, wherein at least part of said variable region is from the sequence as set forth in Figure 6 (SEQ ID NO: 42 and SEQ ID NO:44).

*103 spec*  
<sup>16</sup>15. <sup>2 2 2</sup>[A fragment of the antibody of claim 13, wherein the fragment binds Shiga toxin type 2 and Shiga toxin type 2 variants.]

*103 spec*  
<sup>17</sup>16. The humanized monoclonal antibody of claim 13, wherein said human constant region is selected from group consisting of IgG, IgA and IgM.

*sub B2*  
<sup>18</sup>17. The humanized monoclonal antibody of claim <sup>17</sup>16, wherein said human constant region is IgG.

<sup>19</sup>18. A humanized monoclonal antibody which binds Shiga toxin type 2 and Shiga toxin type 2 variants, comprising a constant region and a variable region, wherein:

said constant region is IgG1-kappa, and

said variable region contains at least part of the sequence as set forth in Figure 6

(SEQ ID NO:42 and SEQ ID NO:44).

<sup>20</sup>19. A humanized monoclonal antibody which binds Shiga toxin type 2 and Shiga toxin type 2 variants, comprising a constant region and a variable region, wherein:

said constant region is IgG1-kappa, and

said variable region contains at least part of the CDR sequences as set forth in Figure 6,

said CDR sequences located as follows:

Heavy Chain CDRs:

(SEQ ID NO:44)

CDR1-aa31-35

CDR2-aa50-66

CDR3-aa99-108

Light Chain CDRs:

(SEQ ID NO:42)

CDR1-aa24-40

CDR2-aa56-62

CDR3-aa95-103

*not a prior*

<sup>21</sup>  
~~20.~~ An expression vector comprising a DNA encoding the variable and constant regions of the light and the heavy chains of the antibody of claim <sup>20</sup>19, where the coding sequences for the variable regions contain at least part of the DNA sequences as set forth in Figure 6 (SEQ ID NO:41 and 43).

<sup>22</sup>  
~~21.~~ A host cell transformed with the expression vector of claim <sup>21</sup>20.

22. A pharmaceutical composition comprising the antibody of claim 1, or fragment or derivative thereof, and a pharmaceutically acceptable carrier or diluent.

23. A method for treating a patient having an infection caused by EHEC or other Shiga toxin producing bacteria comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition of claim 22.

24. A method for reducing illness caused by EHEC or other Shiga toxin-producing bacteria comprising administering to the patient a prophylactically effective amount of the pharmaceutical composition of claim 23.

25. A pharmaceutical composition comprising the antibody of claim 3, or fragment or derivative thereof, and a pharmaceutically acceptable carrier or diluent.

26. A method for treating a patient having an infection caused by EHEC or other Shiga toxin producing bacteria comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition of claim 25.

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27.

A method for reducing illness caused by EHEC or other Shiga toxin-producing bacteria comprising administering to the patient a prophylactically effective amount of the pharmaceutical composition of claim <sup>26</sup>25.

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28.

A pharmaceutical composition comprising the antibody of claim 13, or fragment or derivative thereof, and a pharmaceutically acceptable carrier or diluent.

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29.

A method for treating a patient having an infection caused by EHEC or other Shiga toxin producing bacteria comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition of claim <sup>29</sup>28.

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30.

A method for reducing illness caused by EHEC or other Shiga toxin-producing bacteria comprising administering to the patient a prophylactically effective amount of the pharmaceutical composition of claim <sup>29</sup>28.